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Amgen

Amgen Sluggish in First Quarter as Attention Turns to New Product Candidates

By Zeke Ashton (ZAshton@Fool.com)

REPORT OVERVIEW

- On April 25, Amgen reported results for the first quarter of fiscal 2000. As management predicted, revenues and earnings growth were negatively affected by Y2K-related stockpiling by wholesalers and dialysis providers. Revenues increased by 9% versus the previous year's first quarter to \$814 million, and net income increased 8% to \$266 million.

- Sales of Epogen increased 12% during the quarter to \$440 million. Amgen believes that first-quarter sales of Epogen suffered from approximately \$36 million worth of Y2K-related inventory stockpiling. The company continues to believe that percentage sales growth for Epogen for fiscal 2000 will be in the low teens.

- Sales of Neupogen declined 13% in the quarter to \$250 million. The company estimated that inventory backlog reduced Neupogen sales by about \$59 million in the quarter. The company noted that underlying demand for Neupogen actually increased at a low double-digit rate, and expects percentage growth for Neupogen to be in the mid-single digits for the year.

- Amgen's management expressed some optimism for the full-year results, raising guidance for full-year earnings up a penny per share to the \$1.06 to \$1.08 range.



FOOLISH RATING

Industry Attractiveness	★★★★
Position in Industry	★★★★
Business Quality	★★★★
Investment Predictability	★★★☆☆
Overall Prospects	★★★★☆

Explanation of Criteria on page 4.

QUARTERLY FINANCIALS

(millions, except EPS)	Q1 2000 (A)	Q4 1999
Total Revenues	\$814.1	\$926.9
Gross Profit	\$728.4	\$814.9
R&D	\$189.8	\$242.3
Net Income	\$266.2	\$281.6
EPS (diluted)	\$0.25	\$0.26

ANNUAL FINANCIALS

(millions, except EPS)	1999 (A)	1998
Total Revenues	\$3,340.1	\$2,718.2
Gross Profit	\$2,938.0	\$2,373.0
R&D	\$822.8	\$663.3
Net Income	\$1,096.4	\$863.2
EPS (diluted)	\$1.02	\$0.82

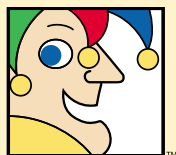
QUOTE & BALANCE SHEET INFORMATION

TTM Range	\$26.06 - \$76.50
Shares Outstanding	1,026.8 million
Market Capitalization	\$66.226 billion
PE Ratio	62.02
Dividend Yield	0.0%
March 31, 2000	
Cash & Short-term Investments	\$1,479.6 million
Total Assets	\$4,264.7 million
Long-term Debt	\$223.0 million
Total Liabilities	\$953.7 million
Shareholder Equity	\$3,311.0 million

AMGEN'S STOCK PRICE OVER THE PAST 12 MONTHS:



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- On April 26, Amgen announced that the U.S. District Court of Massachusetts had granted Amgen's motion for summary judgment in the patent infringement case with Hoechst Marion Roussel (now known as Aventis) and Transkaryotic Therapies (TKT) for claim 1 of U.S. patent number 5,955,422. While this motion is only the first of many events in Amgen's legal defense of its Epogen franchise, it does increase the legal burden on Aventis/Transkaryotic Therapies, which must now attempt to prove the original patent to be invalid.
- On the Research and Development front, Amgen reported expected progress throughout the pipeline, with the acceptance by regulatory authorities for NESP and IL-1ra (Kineret) in the United States and Europe. Amgen plans to launch NESP and IL-1ra in 2001 and 2002. In addition, Amgen filed for regulatory approval for NESP in Canada, Australia, and New Zealand in the first quarter. The company also hopes to file a regulatory submission with the European Medicines Evaluations Agency (EMA) for IL-1ra within the year.
- In addition to the regulatory filing activity with NESP and IL-1ra, Amgen will be presenting Phase 3 data for Abarelix, the company's prostate cancer treatment, at the American Society of Clinical Oncology's annual meeting in May. Abarelix is a result of a partnership with Praecis Pharmaceuticals.

FIRST-QUARTER REVIEW

On April 25, Amgen reported financial results for the fiscal first quarter. While it was not a stellar quarter operationally for Amgen, it is the progress of the company's R&D pipeline that is most important in terms of the long-term outlook. In addition to the earnings report, the other important event in the quarter was the litigation activity, still ongoing, with Aventis/Transkaryotic Therapies. For purposes of organization, let's review the financial performance in the quarter first, R&D highlights second, and a short discussion of the litigation third.

FINANCIAL PERFORMANCE

While Amgen met consensus Street estimates of 26 cents per share, the company would have posted only 23 cents per share had it not been for pretax benefits of approximately \$40 million in the form of increased corporate partner revenue due to the completion of the NESP development program, a tax benefit, and realized gains on some equity investments.

Total product sales came in at \$697 million in the quarter, only about a 1.4% increase over product sales in the first quarter of 1999. Sales were negatively affected by some greater-than-expected Y2K stocking at the provider and wholesaler level. Corporate partner revenues for the quarter were \$74.2 million, a 175% increase over the previous year. Total revenues

were up 9.2% year-over-year to \$814.1 million.

Sales of Epogen were \$440.4 million for the quarter, an increase of 12% versus the previous year. Amgen estimates that about \$36 million in sales was lost due to stockpiling, and the company stated that it expects Epogen growth to come in at low double digits for the full year.

Neupogen sales were much weaker than expected, and actually declined by 13% from the previous year to \$250 million in the quarter. The company estimates that Neupogen sales have been negatively affected by about \$59 million due to Y2K and inventory stockpiling, and stated that Neupogen growth is expected to be in the mid-single digits for the full year. Infergen sales came in at \$6.9 million for the quarter, up 10% year-over-year.

On the expense side, Amgen continues to reduce the cost of sales, increasing gross profit margins to 89.4% in the quarter. Research & Development expenses were basically flat year-over-year, and came in at \$189.8 million, or 23.3% of sales. Selling, general, and administrative costs jumped by 28% over the previous year, as Amgen continues to ramp up sales and marketing in preparation for the expected launch of NESP. Net income for the quarter was \$266.2 million, up 7.7%, translating into net margins of 32.7%.

While the quarter overall was slightly underwhelming relative to expectations, Amgen's management was very upbeat about expected results for the full year, upping its earnings guidance by a penny per share to the \$1.06-1.08 range.

RESEARCH & DEVELOPMENT NEWS

While Amgen management showed optimism for the company for fiscal 2000, it is the continued progression of the R&D pipeline that is the most critical factor to the company's long-range success. On that front, all the news is good news. Amgen announced that the regulatory filings for the use of NESP for anemia for patients with renal failure/insufficiency in the U.S. and Europe have been formally accepted by the respective agencies. The review time is likely to be a year or so in the U.S. and slightly longer in Europe, which points to an expected commercial launch in early 2001. Wall Street is starting to get excited about NESP's potential. Robertson Stephens, for example, has raised its estimates for NESP sales to \$250 million, \$500 million, and \$750 million for 2001-2003. Amgen also filed for NESP approval in Australia and New Zealand during the quarter. Amgen is expected to present clinical trial data concerning the use of NESP for the treatment of cancer at the American Society of Clinical Oncology's (ASCO) annual meeting in May.

Amgen also announced that the FDA has accepted filings for Kineret (IL-1ra) for rheumatoid arthritis in the United States, and the company is expected to file with the EMA in Europe during the course of this year. While Kineret will likely not be a large revenue producer, peak sales could eventually exceed \$100 million.

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In addition to NESP and Kineret, Amgen's clinical trials for two other potential big market drugs, Abarelix and SD-01, are also progressing well. Phase 3 clinical data from studies using Abarelix-depot for prostate cancer and SD-01 data for chemotherapy-related neutropenia will also be presented at ASCO. Amgen is expecting to launch both of these products in 2001 or 2002.

The following updated chart provides an overview of Amgen's R&D pipeline. The data is taken from Amgen's annual report.

OVERVIEW OF AMGEN'S R&D PIPELINE

Product Candidate	Medical Indication	Development Phase
Stemgen*	PBPC mobilization Aplastic anemia	Approved Phase 1 / 2
NESP	Renal insufficiency/ failure Chemotherapy-induced anemia	Filed for approval Phase 2
Kineret	Rheumatoid arthritis	Filed for approval
SD/01	Neutropenia	Phase 3
Abarelix-depot	Prostate cancer Endometriosis	Phase 3 Phase 2
Calcimimetic Program	Primary hyperthyroidism	Phase 2
Leptin	Obesity	Phase 2
KGF	Mucositis	Phase 2
BDNF	Amyotrophic lateral sclerosis	Phase 2
PEG-sTNF-RI	Rheumatoid arthritis	Phase 2
Neuroimmunophilin	Parkinson's disease	Phase 1
OPG	Osteoporosis Bone metastases	Phase 1 Preclinical

* Stemgen has been approved in Australia, Canada, and New Zealand only.

LITIGATION

Amgen is involved in litigation with Aventis (formerly Hoechst Marion Roussel) and Transkaryotic Therapies to determine whether the latter two companies have infringed upon Amgen's Epogen patents in the marketing of Transkaryotic's gene-activated erythropoietin product, GA-EPO. The five patents are U.S. Patent numbers 5,547,933; 5,756,349; 5,955,422; 5,618,698; and 5,621,080.

On April 26, Judge William G. Young of the District Court of Massachusetts granted Amgen's motion for summary judgment of literal infringement, ruling that Aventis and TKT infringes claim 1 of patent 5,955,422. This patent refers to the production of erythropoietin. The judge also ruled that with respect to two claims made with respect to patent number 5,756,349, the court had denied Amgen's request for a summary judgment, and that those claims would be resolved in trial. Beyond that, none of the parties involved has released information pertaining to the case.

The patents mentioned in the press release both refer to the production of erythropoietin. In the case of patent 5,955,422, the summary judgment of infringement is definitely a development in Amgen's favor, as it puts the legal burden on

the infringing party. Aventis and TKT must now prove in court that the patent in question is invalid as it pertains to GA-EPO. While there is long way to go before this litigation is resolved, it appears that Amgen has a formidable wall of patents covering Epogen, and there is every reason to believe that the odds are in Amgen's favor based upon the information available at this time.

INVESTMENT OUTLOOK

Assuming there is no nasty surprise on the litigation front, Amgen looks to be very strongly positioned for future growth. As mentioned in our initial report (released in February), 2000 represents something of a transition year for the company. It appears as though the three candidates with the best chances of becoming blockbuster drugs (NESP, Abarelix, and SD01) are all on target for launch in the next two years. Meanwhile, Amgen foresees continued revenue growth for Epogen and Neupogen at least for the remainder of this year. Overall, the outlook for Amgen remains bright. With the recent fall from its December and January highs, it would appear that Amgen shares offer solid appreciation potential over the mid-to-longer term.

NEWS TIMELINE

04/03/00 (\$59.37) — Amgen names 18-year company veteran Dennis Fenton first executive vice president, heading Research and Operations.

04/21/00 (\$51.31) — Amgen names Steve Odre general counsel and corporate secretary.

04/25/00 (\$54.31) — Amgen reports 9% increase in first-quarter earnings per share and increases earnings per share guidance.

04/26/00 (\$57.25) — Federal judge rules Hoechst and TKT infringe Amgen's EPO patent.

Amgen is a component of The Motley Fool's Now 50 Index.

ABOUT THE FOOLISH ANALYST

Zeke Ashton writes for the Fool's awesome new Fool Research team, kicks in an article a week for the Rule Maker portfolio, and regularly forgets his Fool ID, which is why he can't get into the building half the time. In a previous life, Zeke was an international financial systems consultant in Munich, London, Milan, and Zurich. Zeke enjoys reading, working out, and drinking suspicious-looking concoctions that he claims have beneficial nutritional qualities. A huge baseball fan, Zeke suffers from a recurring dream in which all the other teams in Major League Baseball, in an act of mutual pity, finally allow the Texas Rangers to win the World Series.

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At the time of publication, the writer owned shares of Amgen.

Amgen is currently a holding in The Motley Fool's Rule Breaker Portfolio.

EXPLANATION OF CRITERIA

Industry Attractiveness measures an industry's potential and dynamics, including quality of sales (i.e. gross margins on typical industry sales) and more. **Position in Industry** seeks to measure where a company stands in its industry; is it the top dog, or is it a second-tier follower? Only leaders are rated excellent. **Business Quality** addresses the economics of the specific business being studied. How profitable is it or can it be? What is the potential return on capital in the business?

Investment Predictability takes into account the stability of a business.

Overall Prospects rates the analyst's opinion of the company's and the stock's long-term potential, as well as valuation. This rating wraps up the whole enchilada, from business quality, to management, to industry position and valuation. Long-term is at least three years, but typically much longer.

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4 Jesters: Excellent



3 Jesters: Good



2 Jesters: Fair



1 Jester: Poor

THE NUMBERS

On the next page, you will find a table providing detailed statistics that describe Amgen's financial performance over the last couple of years. Here are some notes pertaining to this table.

- **Return on Assets:** For quarterly return on assets, I used the net income divided by the average total assets over the quarter (Total Assets 1 + Total Assets 2 divided by 2) to obtain a quarterly ROA. I then multiplied this by four to get annualized ROA.
- **Return on Equity:** For quarterly return on equity, I used the same method as for ROA above (substituting shareholder equity for total assets) to get annualized quarterly ROE.
- **Flow Ratio:** The Foolish Flow Ratio is a metric introduced by Tom Gardner in the Rule Maker Portfolio as an indicator of how well a company manages cash. The flow ratio is calculated by taking current assets minus cash and investments, and divided by current liabilities minus short-term debt. The lower the flow ratio, the better control the company has of cash. Rule Maker companies typically have flows of less than 1.25.
- **Cash King Margin:** The Cash King Margin is the new name for the metric previously referred to as Cash Flow Net Margin. This metric was introduced by Matt Richey in the Rule Maker portfolio. It is calculated by taking free cash flow (operating cash flow minus capital expenditures) as a percentage of sales. We like to see cash flow net margin to be as good or better than standard net margin.



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AMGEN FINANCIALS

(in millions, except EPS data)

AMGEN	Q1 '00	Q4 '99	Q3 '99	Q2 '99	Q1 '99	1999	1998	1997
Balance Sheet:								
Cash & Investments	\$1479.6	\$1333.0	\$1524.0	\$1368.3	\$1318.0	\$1,333.0	\$1276.0	\$1026.5
Accounts Receivable	259.1	412.2	300.4	363.6	369.6	412.2	319.9	269.0
Inventory	237.6	184.3	146.9	121.8	117.2	184.3	110.8	109.2
Total Current Assets	2153.6	2065.3	2126.4	2010.8	1973.0	2065.3	1863.3	1543.5
PP&E	1595.3	1553.6	1508.9	1484.0	1482.1	1553.6	1450.2	1186.2
Total Assets	4264.7	4077.6	4036.8	3889.6	3818.3	4077.6	3672.2	3110.2
Accounts Payable	108.7	83.4	100.8	144.0	95.1	83.4	121.6	103.9
Short-term Debt	99.8	99.5	99.7	99.8	99.9	99.5	99.7	30.0
Total Current Liabilities	730.7	831.1	818.3	881.2	851.9	831.1	887.0	741.9
Long-term Debt	223	223	223	223	223	223	223	229
Total Shareholders' Equity	3311.0	3023.5	2995.5	2785.4	2743.4	3023.5	2562.2	2139.3
Income Statement:								
Revenue	814.1	926.9	847.2	820.5	745.5	3340.1	2718.2	2401.0
COGS	85.7	112	98.9	98.8	92.4	402.1	345.2	300.8
Research & Development	189.8	242.3	198.4	194.1	188.0	822.8	663.3	630.8
Interest Income (Expense)	32.2	18.5	22.0	21.2	16.3	73.1	35.7	68.9
Extraordinary Gain (Loss)	0	0	49	0	0	49	(23.0)	157.0
Provision for Income Tax	118.5	103.7	152.8	114.8	98.5	469.8	361.2	217.1
Net Income	266.2	281.6	300	267.6	247.2	1096.4	863.2	644.3
EPS (Diluted)	0.25	0.26	0.28	0.25	0.23	1.02	0.81	0.58
Revenue Growth (Y/Y)	9.2%	22.6%	20.9%	24.9%	23.1%	22.9%	13.2%	7.2%
EPS Growth (Y/Y)	8.7%	18.2%	33.3%	22.0%	31.4%	25.1%	39.3%	(3.3%)
Diluted Shares	1085.7	1079.2	1078.8	1073.8	1080.9	1078.3	1057.4	1098.4
Cash Flow Statement:								
Operating Cash Flow	294.3	191.3	318.9	364.4	200.7	1075.3	1041.5	902.9
Net Capital Expenditures	92.5	92.9	64.3	70.7	76.3	304.2	407.8	387.8
Free Cash Flow	201.8	98.4	254.6	293.7	124.4	771.1	407.8	387.8
Computed Figures:								
Effective Tax Rate	30.8%	26.9%	33.7%	30.0%	28.5%	31.4%	29.5%	29.4%
Return on Assets	25.5%	27.8%	30.3%	27.8%	26.4%	28.3%	25.5%	20.7%
Return on Equity	33.6%	37.4%	41.5%	38.7%	37.3%	39.3%	36.7%	31.9%
Cash & Inv./ Debt	6.60	4.13	6.83	4.24	4.08	4.13	3.95	3.96
Gross Profit Margin	89.4%	87.9%	88.3%	88.0%	86.6%	87.9%	87.3%	87.4%
Net Profit Margin	32.7%	30.4%	35.4%	32.6%	33.2%	32.8%	31.8%	26.8%
Flow Ratio	1.07	1.00	0.84	0.82	0.87	1.00	0.75	0.73
Cash King Margin	24.8%	10.6%	30.1%	35.6%	16.7%	23.1%	23.3%	21.4%

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